

**Senator Curtis S. Bramble** proposes the following substitute bill:

**PHARMACY PRACTICE ACT REVISIONS**

2012 GENERAL SESSION

STATE OF UTAH

**Chief Sponsor: Curtis S. Bramble**

House Sponsor: Evan J. Vickers

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**LONG TITLE**

**General Description:**

This bill amends the exemptions from licensure in the Pharmacy Practice Act.

**Highlighted Provisions:**

This bill:

- ▶ defines a cancer drug treatment regimen;
- ▶ exempts an oncologist from the licensing requirements under the Pharmacy Practice Act when the oncologist provides a cancer drug treatment regimen to a patient who is currently undergoing chemotherapy in an outpatient clinic;
- ▶ excludes Schedule I, II, and III drugs from the drugs an oncologist may provide to a patient under the licensing exemption from the Pharmacy Practice Act; and
- ▶ includes assistants to the oncologist who are under the supervision of the oncologist in the licensing exemption from the Pharmacy Practice Act.

**Money Appropriated in this Bill:**

None

**Other Special Clauses:**

None

**Utah Code Sections Affected:**

AMENDS:



26           **58-17b-309**, as last amended by Laws of Utah 2011, Chapter 76



27  
28 *Be it enacted by the Legislature of the state of Utah:*

29           Section 1. Section **58-17b-309** is amended to read:

30           **58-17b-309. Exemptions from licensure.**

31           (1) For purposes of this section:

32           (a) "Cancer drug treatment regimen":

33           (i) means a prescription drug used to treat cancer, manage its symptoms, or provide  
34 continuity of care for a cancer patient;

35           (ii) includes:

36           (A) a chemotherapy drug administered intravenously, orally, rectally, or by dermal  
37 methods; and

38           (B) a drug used to support cancer treatment, including to treat, alleviate, or minimize  
39 physical and psychological symptoms or pain, or to improve patient tolerance of cancer  
40 treatments or prepare a patient for a subsequent course of therapy; and

41           (iii) does not mean a drug listed under federal law as a Schedule I, II, or III drug.

42           ~~(a)~~ (b) "Cosmetic drug":

43           (i) means a prescription drug that is:

44           (A) for the purpose of promoting attractiveness or altering the appearance of an  
45 individual; and

46           (B) listed as a cosmetic drug subject to the exemption under this section by the division  
47 by administrative rule; and

48           (ii) does not include a prescription drug that is:

49           (A) a controlled substance;

50           (B) compounded by the physician; or

51           (C) prescribed or used for the patient for the purpose of diagnosing, curing, mitigating,  
52 treating, or preventing a disease.

53           ~~(b)~~ (c) "Injectable weight loss drug":

54           (i) means an injectable prescription drug:

55           (A) prescribed to promote weight loss; and

56           (B) listed as an injectable prescription drug subject to exemption under this section by

57 the division by administrative rule; and

58 (ii) does not include a prescription drug that is a controlled substance.

59 ~~(c)~~ (d) "Prescribing practitioner" means an individual licensed under:

60 (i) Chapter 31b, Nurse Practice Act, as an advanced practice registered nurse with

61 prescriptive practice;

62 (ii) Chapter 67, Utah Medical Practice Act;

63 (iii) Chapter 68, Utah Osteopathic Medical Practice Act; or

64 (iv) Chapter 70a, Physician Assistant Act.

65 (2) In addition to the exemptions from licensure in Section 58-1-307, the following  
66 individuals may engage in the acts or practices described in this section without being licensed  
67 under this chapter:

68 (a) a person selling or providing contact lenses in accordance with Section 58-16a-801;

69 (b) an individual engaging in the practice of pharmacy technician under the direct  
70 personal supervision of a pharmacist while making satisfactory progress in an approved  
71 program as defined in division rule;

72 (c) a prescribing practitioner who prescribes and dispenses a cosmetic drug or an  
73 injectable weight loss drug to the prescribing practitioner's patient in accordance with  
74 Subsection (4); ~~and~~

75 (d) an optometrist, as defined in Section 58-16a-102, acting within the optometrist's  
76 scope of practice as defined in Section 58-16a-601, who prescribes and dispenses a cosmetic  
77 drug to the optometrist's patient in accordance with Subsection (4)~~[-]; and~~

78 (e) (i) a prescribing practitioner who:

79 (A) treats a patient who is currently undergoing chemotherapy in an outpatient clinic  
80 setting;

81 (B) prescribes a cancer drug treatment regimen to the patient;

82 (C) determines that providing the cancer drug treatment regimen to the patient in the  
83 outpatient clinic setting is in the best interest of the patient, or provides better access to care for  
84 the patient;

85 (D) discloses to the patient that the cancer drug treatment regimen may be obtained  
86 from a pharmacy unaffiliated with the prescribing practitioner;

87 (E) does not directly or indirectly mark up, charge a commission, or make a profit on

88 providing the cancer drug regimen, but may obtain payment for expenses and services related  
89 to providing the cancer drug regimen;

90 (F) provides the cancer drug treatment regimen to the patient, or directs another person  
91 under Subsection (2)(e)(ii) to provide the cancer drug treatment regimen to the patient;

92 (G) is certified or eligible to be certified by the American Board of Internal Medicine  
93 in medical oncology;

94 (H) reports to the Utah Controlled Substance Database in the same manner as required  
95 by Section 58-37f-203, and follows labeling, recordkeeping, patient counseling, and storage  
96 requirements established by administrative rule adopted by the division in consultation with the  
97 board; and

98 (I) for drugs described in Subsection (1)(a)(ii)(B) only, follows the USP-NF ~~§~~ → [979]  
98a 797 ←~~§~~

99 standards for sterile compounding if the drug dispensed to the patient is reconstituted or  
100 compounded; and

101 (ii) a person who is not a prescribing practitioner who:

102 (A) is employed as a healthcare provider by a prescribing practitioner or the outpatient  
103 clinic setting in which the prescribing practitioner works and is acting within the individual's  
104 scope of practice;

105 (B) is acting under the direction of a prescribing practitioner who is immediately  
106 available on site for any necessary consultation, and who has complied with Subsection  
107 (2)(e)(i);

108 (C) prepares or provides the cancer drug treatment regimen to the patient at the  
109 outpatient clinic setting; and

110 (D) follows Subsections (2)(e)(i)(E) and (H).

111 (3) In accordance with Subsection 58-1-303(1)(a), an individual exempt under  
112 Subsection (2)(b) must take all examinations as required by division rule following completion  
113 of an approved curriculum of education, within the required time frame. This exemption  
114 expires immediately upon notification of a failing score of an examination, and the individual  
115 may not continue working as a pharmacy technician even under direct supervision.

116 (4) A prescribing practitioner or optometrist is exempt from licensing under the  
117 provisions of this part if the prescribing practitioner or optometrist:

118 (a) (i) writes a prescription for a drug the prescribing practitioner or optometrist has the

119 authority to dispense under Subsection (4)(b); and

120 (ii) informs the patient:

121 (A) that the prescription may be filled at a pharmacy or dispensed in the prescribing  
122 practitioner's or optometrist's office;

123 (B) of the directions for appropriate use of the drug;

124 (C) of potential side-effects to the use of the drug; and

125 (D) how to contact the prescribing practitioner or optometrist if the patient has  
126 questions or concerns regarding the drug;

127 (b) dispenses a cosmetic drug or injectable weight loss drug only to the prescribing  
128 practitioner's patients or for an optometrist, dispenses a cosmetic drug only to the optometrist's  
129 patients; and

130 (c) follows labeling, record keeping, patient counseling, and storage requirements  
131 established by administrative rule adopted by the division in consultation with the boards listed  
132 in Subsection (5)(a).

133 (5) (a) The division, in consultation with the board under this chapter, the Physician  
134 Licensing Board, the Osteopathic Physician Licensing Board, the Physician Assistant Licensing  
135 Board, the Board of Nursing, and the Optometrist Licensing Board shall adopt administrative  
136 rules pursuant to Title 63G, Chapter 3, Utah Administrative Rulemaking Act to designate:

137 (i) the prescription drugs that may be dispensed as a cosmetic drug or weight loss drug  
138 under this section; and

139 (ii) the requirements under Subsection (4)(c).

140 (b) When making a determination under Subsection (1)~~(a)~~(b), the division and boards  
141 listed in Subsection (5)(a), may consider any federal Food and Drug Administration indications  
142 or approval associated with a drug when adopting a rule to designate a prescription drug that  
143 may be dispensed under this section.

144 (c) The division may inspect the office of a prescribing practitioner or optometrist who  
145 is dispensing under the provisions of this section, in order to determine whether the prescribing  
146 practitioner or optometrist is in compliance with the provisions of this section. If a prescribing  
147 practitioner or optometrist chooses to dispense under the provisions of this section, the  
148 prescribing practitioner or optometrist consents to the jurisdiction of the division to inspect the  
149 prescribing practitioner's or optometrist's office and determine if the provisions of this section

150 are being met by the prescribing practitioner and optometrist.

151 (d) If a prescribing practitioner or optometrist violates a provision of this section, the  
152 prescribing practitioner or optometrist may be subject to discipline under:

153 (i) this chapter; and

154 (ii) (A) Chapter 16a, Utah Optometry Practice Act;

155 (B) Chapter 31b, Nurse Practice Act;

156 (C) Chapter 67, Utah Medical Practice Act;

157 (D) Chapter 68, Utah Osteopathic Medical Practice Act; or

158 (E) Chapter 70a, Physician Assistant Act.

159 (6) Except as provided in Subsection (2)(d), this section does not restrict or limit the  
160 scope of practice of an optometrist or optometric physician licensed under Chapter 16a, Utah  
161 Optometry Practice Act.